

Agenda Radiological Devices Panel Meeting

February 3, 2004

Purpose of the Meeting - To discuss, make recommendations and vote on a premarket approval application (PMA P030012) for a computer aided detection device that assists a physician in identifying solid nodules in CT images of the lung.

Closed Session

8:30 – 8:35	Call to order– Minesh P. Mehta, M.D.
8:35 – 9:00	Briefing on Current Investigational Devices - Robert A. Phillips, Ph.D. and RADB Staff

Open Session

9:00 – 9:20	Call to order and the Panel Introduction – Minesh P. Mehta, M.D. FDA Introductory Remarks - Robert J. Doyle, Executive Secretary Update on FDA Radiology Activities - Robert A. Phillips, Ph.D.
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Open Public Hearing

9:20 – 9:50	Open Public Hearing: interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.
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Open Committee Discussion

9:50 – 10:00	Charge to the Panel - Minesh P. Mehta, M.D.
10:00 – 10:40	Overview of Contemporary ROC Methods – Robert F. Wagner, Ph.D.
10:45 – 11:45	Presentations on P030012 by sponsor Introduction – Kathy O'Shaughnessy, PhD Current Clinical Practice – Heber MacMahon, MD Device Description and Clinical Trial Introduction – Ronald Castellino, MD Clinical Study – Dave Miller User Experience – Pablo Delgado, MD Summary – Kathy O'Shaughnessy, PhD

11:45 - 12:45 Lunch

12:45 – 1:45 Presentations on P030012 by FDA

- PMA Overview - Robert Phillips, Ph.D.
- Clinical Background - William Sacks, Ph.D., M.D
- Clinical Results - Nicholas Petrick, Ph.D.
- PMA Review Summary - William Sacks, Ph.D., M.D

1:45 – 2:15 Reports by Panel Lead Reviewers

- David Stark, M.D.
- Brent Blumenstein, Ph.D.

2:15 – 2:30 Presentation of FDA Questions

2:30 – 2:45 Break

2:45 – 3:45 Panel Discussion

Open Public Hearing

3:45 – 4:15 Open Public Hearing: interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Open Committee Deliberations

4:15 – 4:30 Panel Recommendation(s) and vote

4:30 Adjourn